APR 1 8 2001

510(k) Summary

PRYM MEDICAL Ltd.

Dornir™ LC-1 CPAP System

510(k) Number K010704

Submitter's Name:

PRYM MEDICAL Ltd.
12 Hamada Street
Beit Hatamar
Rehovot 76703, Israel
Tel: 972-8-931-6450
Fax: 972-8-931-6470

Contact Person:

Shoshana Friedman, RAC
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
Tel: 972-9-7718130
Fax: 972-9-7718131

Trade Name:

Dornir™ LC-1 CPAP System

Classification Name:

Ventilator, Non-Continuous

Classification:

Non-continuous ventilators are class II devices (Product Code BZD).

Predicate Device:

The Dornir™ LC-1 CPAP System is substantially equivalent to the Sansibar™ CPAP System (Prym Medical Ltd.) cleared under K000888.

Indication for use:

The Dornir™ LC-1 CPAP System is indicated for the treatment of adult Obstructive Sleep Apnea (OSA).

Device Description:

The Dornir™ LC-1 CPAP System is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is by the delivery of Continuous Positive Airway Pressure between 4 and 20 cmH_2O to prevent airway obstruction.

The Dornir™ LC-1 CPAP System has two main user accessible controls, on/off and ramp time, and three multifunctional control keys for menu navigation and user settings. The pressure setting is set by prescription and is locked-out from the end user's reach. The device is designed for use with a remote control and a remote signal interface.

Substantial Equivalence:

The Dornir™ LC-1 CPAP System is substantially equivalent to the Sansibar™ CPAP System; in fact, the Dornir™ LC-1 CPAP System is a simpler model of the Sansibar™ CPAP System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

PRYM Medical, Ltd.
c/o Ms. Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373, Israel

Re: K010704
Trade Name: Dornir™ LC-1 CPAP System
Regulatory Class: II (two)
Product Code: BZD
Dated: April 1, 2001
Received: April 6, 2001

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K010704

Device Name: Dornir™ LC-1 CPAP System

Indications for Use:

The Dornir™ LC-1 CPAP System is indicated for the treatment of adult Obstructive Sleep Apnea (OSA).

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010704

Prescription Use X (Per 21 CFR 801.109) OR Over the Counter Use_____